# FDA Preliminary Public Health Notification*: Update of Information about *Ralstonia* spp. Associated with Vapotherm® Respiratory Gas Administration Device

Date: December 20, 2005

Original Publication: October 27, 2005 (http://www.fda.gov/cdrh/safety/102705-vapotherm.html

Dear Health Care Practitioner:

CDC's MMWR publication of October 21, 2005 and FDA's Preliminary Public Health Notification of October 27, 2005 alerted practitioners to an association between the Vapotherm® Respiratory Gas Administration devices and the occurrence of positive *Ralstonia* spp. cultures. Since the October 27, 2005 notification, FDA has become aware of additional *Ralstonia spp.* cultures from these devices and from exposed patients. We believe the exposure of patients to *Ralstonia spp.* is a significant public health problem.

## Recommendations

- We advise the use of alternative devices until the source of the contamination has been identified**.**
- We also advise that patients who have been exposed to the Vapotherm system be monitored for signs and symptoms that may suggest infection. Signs and symptoms of *Ralstonia* infection are similar to those seen in any other bacterial infection. These may include, but are not limited to, changes in temperature, poor feeding, irritability, and changes in hematologic indices. Clinicians may want to consider *Ralstonia* infection in the differential diagnosis of symptomatic patients even if the organism has not been isolated.

## Finding Alternative Devices

Alternative devices can be found on the FDA web site http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Several heated humidifiers on the list that are used with infant or adult ventilators have specifications similar to the Vapotherm device, and use heated outlet tubes. The list can be searched using "BTT" in the "Product Code" field. Humidifiers will require a gas source, connectors, and a patient interface (mask or nasal cannula) to make a complete system for administration of breathing gas.

## Current Information

Reports to the FDA and the CDC from more than two dozen hospitals in 16 states indicate that some Vapotherm devices are colonized by *Ralstonia spp.* The bacteria have been cultured from unused Vapotherm® cartridges, from Vapotherm® systems that have

been disinfected according to the original instructions for use, and from devices disinfected according to newly issued instructions provided by the firm. The bacteria have also been isolated from patients exposed to Vapotherm® devices. Cultures of unused Vapotherm® cartridges performed at two hospitals also yielded Ralstonia. However, cultures of other unused cartridges from some of the same lots performed by the cartridge manufacturer and by CDC did not reveal any organisms.

Testing is being conducted to determine the source of *Ralstonia* spp. contamination and to evaluate new disinfection protocols. As more information from that testing becomes available, we will update this notification.

The FDA continues to collaborate with the CDC to determine the scope of the contamination with *Ralstonia spp.*, and other opportunistic pathogens. CDC has updated the MMWR (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm54e1220a1.htm).

## History

In August 2005, a Pennsylvania healthcare facility reported isolation of *Ralstonia* spp. in cultures obtained from several patients using the Vapotherm® 2000i. Surveillance conducted by the CDC identified additional institutions that have recovered *Ralstonia* spp. from clinical specimens or Vapotherm® machines. This information was published in the October 21, 2005 issue of a CDC MMWR (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5441a5.htm). In response, Vapotherm® issued new infection control procedures intended to reduce the risk of infectious disease transmission.

Testing of devices subjected to the chlorine dioxide disinfection protocol provided by the manufacturer for disinfecting Vapotherm® devices showed that the method may not achieve sustained bacterial control. On October 27, 2005, the FDA published a Preliminary Public Health Notification (http://www.fda.gov/cdrh/safety/102705-vapotherm.html) informing the health care community of these events. CDC updated the October 21, 2005 MMWR on November 4, 2005. (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5443a4.htm)

## Information on Ralstonia

Ralstonia species are gram-negative bacteria that can be found in the environment, primarily in water, soil, and on plants and are occasionally isolated from clinical samples (including respiratory secretions of cystic fibrosis patients). These organisms were formerly included in the genus Pseudomonas or Burkholderia, but DNA characterization has revealed them to be a distinct genus. The organism grows readily on media routinely used by clinical microbiology laboratories (trypticase soy agar with 5% sheep blood or MacConkey agar). However, Ralstonia spp. can be mis-identified using both manual biochemical tests and automated identification systems. When this occurs, they are generally identified as Burkholderia species or, less often, as non-aeruginosa Pseudomonas species.

## Reporting Contamination

Clinicians are encouraged to report cases of colonization or infection with *Ralstonia* spp. or related bacteria in patients using any Vapotherm® 2000 respiratory gas administration device. You should report cases directly to the device manufacturer.

You should also report these cases and any other adverse events related to medical devices to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch one of four ways: online at www.fda.gov/Medwatch/report.htm ; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

In addition, we recommend that you report these cases to local or state health departments, or to the CDC at 1-800-893-0485.

## FDA Contact

Office of Surveillance and Biometrics (HFZ-510)
1350 Piccard Drive, Rockville, Maryland, 20850
Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov

Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

FDA medical device Public Health Notifications are available on the Internet at http://www.fda.gov/cdrh/safety.html. You can also be notified through email on the day the safety notification is released by subscribing to our list server. To subscribe, visit: http://list.nih.gov/archives/dev-alert.html.

Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

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